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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,754	04/30/2002	Koji Yamauchi	SAEGU98.001APC	8824
20995	7590	02/24/2005		EXAMINER
				YOON, TAE H
			ART UNIT	PAPER NUMBER
			1714	

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/019,754	YAMAUCHI ET AL.
	Examiner Tae H. Yoon	Art Unit 1714

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 28 December 2004.  
 2a) This action is FINAL.                            2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 3,6-9 and 11-25 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 3,6-9,11-20,22 and 24 is/are rejected.  
 7) Claim(s) 21, 23 and 25 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

Applicant has stated that the instant invention is direct to either two-layered or one unified body of two components artificial dura mater formed of an amorphous or low crystallinity and structural reinforcement having the recited properties by an integral molding utilizing bonding, fusion or impregnation. However, further consideration of the art of record has yielded following rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 3, 6-9 and 11-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14, 16 and 17 of U.S. Patent No. 6,514,291. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copolymer forming an artificial dura mater of said patent encompasses the instant amorphous and low crystalline polymer as evidenced by the same elastic modulus claimed in the instant claim 8 and because the recited "comprising" in claim 1 of said patent encompasses the instant composite structure inherently.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recited "melting" is incorrect since a solvent does not melt a polymer but dissolve.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 6-9, 11-16 and 20 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Taira et al (US 5,861,034).

Applicant has asserted that the dura mater of Taira et al is three-layered structure rather than the instant two-layer or one unified body of two components.

However, the integrated dura mater made by hot pressing at 110°C under 190 kg/cm<sup>2</sup> in example 2 of Taira et al inherently yields the instant integrated one unified body of two components since a lactic acid and  $\epsilon$ -caprolactone copolymer of said example 2 would at least impregnate or flow through the needle punched the plain polyglycolic acid yarn at such temperature and pressure. Thus two sheets would bond or fuse each other. Said lactic acid and  $\epsilon$ -caprolactone copolymer of said example 2 falls within the scope of invention as evidenced by the instant pages 11-12 (molar ratio and average molecular weight). Thus, said lactic acid and  $\epsilon$ -caprolactone copolymer inherently meets the instantly recited crystallinity, elastic modulus and Tg. Also, Taira et al teach the reinforcement is *integrated* with the sheet of the invention at col. 2, lines 19-21 as in the instant invention.

With respect to the elastic modulus of the structural reinforcement, Taira et al teach a tensile modulus of 14.88 MPa for the composite in table 1 and said lactic acid and  $\epsilon$ -caprolactone copolymer has an elastic modulus lower than 10 MPa. Thus, said high tensile modulus of 14.88 MPa would be from the presence of said structural reinforcement and structural reinforcement inherently possesses the recited elastic modulus. Also, a polymer for the structural reinforcement has a higher melting point than the (co)polymer sheet (col. 2, lines 31-34), and thus it has higher Tg than said (co)polymer sheet. Said polyglycolic acid yarn inherently possesses the recited Tg.

Thus, the instant invention lacks novelty.

Claims 3, 6-9, 11-16 and 20 are rejected under 35 U.S.C. 103(a) as obvious over Taira et al (US 5,861,034) and Williams et al (US 6,548,569).

Williams et al teach that polyglycolic acid (PGA) of Taira et al has a Tg of 35 °C in table 1, col. 37 which supports the examiner's position in above rejection.

Claims 21, 23 and 25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 22 and 24 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action, and if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tae H. Yoon whose telephone number is (571) 272-1128. The examiner can normally be reached on Mon-Thu.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on (571) 272-1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Tae H Yoon  
Primary Examiner  
Art Unit 1714

THY/February 17, 2005